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EXAMINER

ROARK, JESSICA H

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/17/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/649,108

Applicant(s)

CHEN, LIEPING

Examiner

Jessica H. Roark

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 June 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-51 is/are pending in the application.

4a) Of the above claim(s) 1-5, 8 and 10 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 6, 7, 9, 49-51 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 20 November 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.

6) Other: _____

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 6/16/03, is acknowledged.

Claim 6 has been amended.

Claim 51 has been added.

Claims 1-51 are pending.

2. Claims 1-5, 8 and 10-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Claims 6-7, 9 and 49-51 are under consideration in the instant application.

3. This Office Action will be in response to applicant's arguments, filed 6/16/03 (Paper No. 23).

The rejections of record can be found in the previous Office Action (Paper No. 20).

It is noted that New Grounds of Rejection are set forth herein.

Claim Rejections - 35 USC § 112 first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Applicant's arguments regarding adequate written support for the recited species of 65 degrees C in view of a disclosed range on page 16 at lines 6-8 of 50-65 degrees C has been fully considered. In view of the disclosure of the species of 65 degrees C as the upper limit, it does appear that the species of 65 degrees C has adequate written support in the specification as filed.

The previous rejection of claims 6-7, 9 and 49-50 under 35 U.S.C. 112, first paragraph, *New Matter*, is therefore withdrawn.

6. Claims 6-7, 9 and 49-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons:*

Art Unit: 1644

As acknowledged *supra*, the specification at page 16, lines 6-8, does appear to provide adequate written support for wash conditions employing 0.2 X SSC and 0.1% SDS at 50-65 degrees C. However, the specification does not appear to provide an adequate written description of a wash at 60-65 degrees C. A subgenus drawn to the range 60-65 is not clearly supported by adequate blaze marks in the specification as filed such that the skilled artisan could pick out the range of 60-65 from the disclosed range of 50-65. The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action, or to clearly point out the written support for the instant limitations.

Alternatively, Applicant is invited to amend the claim to recite the range disclosed on page 16 at line 8 to obviate this rejection.

Claim Rejections – 35 U.S.C. §§ 102 and 103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. The Declaration of Dr. Chen filed on 6/16/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Freeman et al. reference for the following reasons:

A) The Freeman et al. reference is a U.S. patent application publication of a pending application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings.

B) The Declaration also fails to clearly establish that the acts performed were in the United States of America because no indication is given that “this country” as mentioned in Section 2 of the Declaration is in fact the United States of America.

C) The manuscript provided as evidence of conception and reduction to practice is not commensurate with the scope of the claims of Freeman et al.

It appears that Applicant should provide a showing under 37 C.F.R 1.608 rather than correct the deficiencies noted in points (B) and (C) supra in a new Declaration under 37 C.F.R 1.131.

9. Claims 6-7, 9 and 49-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Freeman et al. (US2002/0102651, of record, see entire document).

Applicant argues in the Remarks filed 6/16/03 that the Declaration under 37 C.F.R. 1.131 of DR. Chen is sufficient to establish that Freeman et al. is not prior art. However, for the reasons set forth supra the Declaration has not be found sufficient.

Freeman et al teach and claim the human B7-4 polypeptide of SEQ ID NO:4 encoded by SEQ ID NO:1 (see entire document, including claims, sequence listing and Figures). SEQ ID NO:4 is taught at paragraphs 313-315 to costimulate T cells.

The complement of the nucleic acid of SEQ ID NO:1 of Freeman et al. would hybridize to SEQ ID NO:1 of Freeman et al. after a wash at 65 degrees C in a buffer containing 0.2x SSC and 0.1% SDS; therefore SEQ ID NO:1 itself is a nucleic acid that hybridizes as recited in instant claim 1 and encodes a polypeptide which co-stimulates a T cell.

Freeman et al. also teach and claim polypeptide variants which are encoded by nucleic acids which hybridize under the stringent conditions recited to a nucleic acid molecule consisting of SEQ ID NO:1 or 3 of Freeman et al. (e.g., claim 12(b) and paragraphs 82-84).

SEQ ID NO:4 of Freeman et al. is a polypeptide of 290 amino acids that is identical to instant SEQ ID NO:1 over its full length. Therefore, the B7-4 polypeptide of Freeman et al. is a polypeptide comprising: amino acid residue 23 (or amino acid residue 30) to amino acid residue 290 of instant SEQ ID NO:1; SEQ ID NO:1 itself; and SEQ ID NO:10 (the extracellular domain of SEQ ID NO:1).

Freeman et al. also teach polypeptides which differ from the B7-4 polypeptide set forth in SEQ ID NO:4 of Freeman et al. by one or more conservative amino acid substitutions (see e.g., paragraphs 88-93)

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the B7-4 polypeptides of Freeman et al.

The reference teachings thus anticipate the instant claimed invention.

10. Applicant Note: A declaration under 37 CFR 1.131 or 1.132 would *not* be sufficient to overcome the rejection of the instant claims as being anticipated by Freeman et al. (US2002/0102651). See 37 C.F.R 1.608(b).

Conclusion

11. No claim is allowed.
12. Applicant's IDS, filed 6/16/03, is acknowledged.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica H. Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday, 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
July 15, 2003

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PRIMARY EXAMINER

TECH CENTER 1600
7/16/03